IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., Inc. Plaintiff, v. RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Defendant.	C.A. No. 07-229 (GMS)
RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Counterclaim Plaintiff, v. MERCK & CO., Inc. Counterclaim Defendant.	

RANBAXY'S MOTION FOR LEAVE TO AMEND
AND SUPPLEMENT ITS ANSWER

Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy"), respectfully submit this Motion for Leave, pursuant to Rules 15(a) and 15(d) of the Federal Rules of Civil Procedure, to amend their answer 1) to present an affirmative defense and counterclaim that U.S. Patent 5,147,868 is unenforceable due to inequitable conduct before the United States Patent and Trademark Office, and 2) to supplement its original pleading to reflect the current facts of the case, i.e., reflect that two additional ANDAs directed to the same drug product as in the original ANDA (but

in different packaging forms) were filed in summer, 2007, disclosed to Merck shortly thereafter, and that discovery has proceeded on them since that time.

Merck does not oppose the addition of the inequitable conduct claims set forth in the Eighth Defense and Counterclaim IV. As to the supplemental amendment to the original answer to include additional facts, Merck's counsel advised that it had not had an opportunity to consult with Merck and, therefore, could not provide Merck's position with respect to the supplementation prior to this filing.

Pursuant to Local Civil Rule 15.1, copies of the 1) proposed First Amended and Supplemental Answer and Counterclaims and 2) a redlined form of the First Supplemental Amended Answer and Counterclaims, indicating in what respect it differs from Ranbaxy's earlier filed Answer and Counterclaims, are attached as Exhibits A and B to this Motion for Leave.

I. THE INEQUITABLE CONDUCT ALLEGATIONS ARE UNOPPOSED AND SHOULD BE ALLOWED.

Leave to amend pleadings as sought by this motion shall be freely given when justice so requires. Fed. R. Civ. P. 15(a). The Court may deny leave to amend if delay in seeking amendment is undue, motivated by bad faith, or prejudicial to the opposing party. *See Adams v. Gould, Inc.,* 739 F.2d 858, 864 (3d .Cir 1984); *see also Foman v. Davis,* 371 U.S. 178, 182 (1962). The Court may also refuse to permit an amendment that fails to state a cause of action. *Massary v. General Motors Corp.,* 706 F.2d 111, 125 (3d Cir. 1983).

As demonstrated below (1) Merck will not be prejudiced if Ranbaxy is allowed to amend its answer to assert inequitable conduct, and (2) the proposed amendments raise

meritorious claims, the factual bases of which are numerous were developed and determined over the last several months.

A. Ranbaxy Has Not Delayed In Asserting Inequitable Conduct.

The passage of time, without more, does not require that a motion to amend a complaint be denied. *See Adams,* 739 F.2d at 868. Ranbaxy's original answer was filed just six months ago. The pretrial scheduling order originally provided that the parties could present motions to amend the pleadings until January 4, 2008, and the Court subsequently granted the parties' stipulated motion to extend that date to January 11, 2008. Additionally, the cut-off for fact discovery is not until May 31, 2008. The factual bases of the inequitable conduct defense are largely rooted in public file histories of the patent-in-suit and a number of closely related Merck patents. Ranbaxy had hoped to take further discovery on the facts before finalizing this defense, but to date Merck's document production remains lacking and depositions of the inventors, prosecuting attorneys and other fact witnesses have not yet occurred.

Further, inequitable conduct is a serious charge, not to be lightly asserted. *See FMC Corp. v. Manitowoc Co.,* 835 F.2d 1411, 1415 (Fed. Cir. 1987). In contrast to affirmative defenses and counterclaims of invalidity and non-infringement, inequitable conduct must be pled with particularity in accordance with Rule 9(b) of the Federal Rules of Civil Procedure. *EMC Corp. v. Storage Technology Corp.,* 921 F. Supp. 1261, 1263 (D. Del. 1996). Heeding the Federal Circuit's admonition and in order to comply with the requirement for particularity, Ranbaxy did not raise its inequitable conduct defense and counterclaim until it had sufficient evidence to do so. Ranbaxy's presently proposed inequitable conduct assertion is based on information available at this time, noting the

stage of discovery as discussed above, and is based on voluminous file histories spanning many years of prosecution leading to the '868 patent and the closely related patents and applications discussed in the proposed amendment. Given the state of discovery, Ranbaxy reserves the right to supplement this defense if appropriate.

B. Merck Is Not Prejudiced By Adding The Affirmative Defense and Counterclaim.

Merck will not be able to show that it has been prejudiced by allowing the defense of inequitable conduct and the accompanying counterclaim of unenforceability to be asserted now. The Third Circuit has stated that to make the required showing of prejudice, regardless of the stage of proceedings, a challenging party must demonstrate that its ability to present its case would be seriously impaired if the amendment were allowed. *Dole v. Arco Chemical Co.,* 921 F.2d 484, 488 (3d. Cir. 1992); *see also Bechtel v. Robinson,* 886 F.2d 644, 652 (3d Cir. 1989) ("the non-moving party must do more than merely claim prejudice; it must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence..."). Merck cannot demonstrate any such impairment here. It has ample access to both its own documents, employees, prosecution counsel, and thus has available all information and facts necessary to defend against the inequitable conduct claim. Further, Merck has no basis to seek discovery from Ranbaxy regarding inequitable conduct since this claim is based solely on Merck's own knowledge and acts during prosecution of the applications leading to the '868 patent.

C. Ranbaxy's Proposed Amended Answer Is Well-Grounded In Fact And Law And Not Futile.

Inequitable conduct before the PTO is a well recognized basis of finding a patent unenforceable. *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066,

1070 (Fed. Cir. 1992); *Life Techs., Inc. v. Clontech Lab, Inc.*, 224 F.3d 1320, 1324 (Fed. Cir. 2000); *see also ISCO Int'l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, (D. Del. 2003). A patent applicant engages in inequitable conduct when it breaches its duty to prosecute an application with candor, good faith and honesty, and does so with an intent to mislead the PTO. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). The underlying breach can take a number of forms and may include affirmative misrepresentation of a material fact, submission of false information, or failure to disclose material information. *Id.* Particularly relevant to the instant case, the Federal Circuit has emphasized the importance of the duty to disclose co-pending patent applications, when a double patenting rejection is even merely plausible. *See McKesson Info. Solutions, Inc. v. Bridge Med. Inc.*, 487 F.3d 897 (Fed. Cir. 2007); *see also Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003) and *Akron Polymer Container Corp. v. Excel Container, Inc.*, 48 F.3d 1380, 1382 (Fed. Cir. 1998).

The proposed Eighth Defense properly pleads with particularity each element required for inequitable conduct. Numerous instances of Merck's concealment of co-pending patent applications and patents that were highly material to examination of the applications leading to the issuance of the '868 patent are specifically detailed. The Eighth Defense also details grounds on which an inference of intent to deceive the PTO should be drawn from Merck's systematic and protracted concealment of highly material information.

Proposed Counterclaim IV mirrors the Eighth Defense, and also fully satisfies the pleading requirements necessary to assert inequitable conduct as a basis for unenforceability of the '868 patent.

Ranbaxy respectfully requests the Court to grant leave to file the proposed Amended and Supplemental Answer and Counterclaims, and an opportunity to present the complete facts regarding Merck's inequitable conduct in obtaining the '868 patent.

II. THE SUPPLEMENTAL AMENDMENT SHOULD BE PERMITTED.

Pursuant to Rule 15(d) of the Federal Rules of Civil Procedure, Ranbaxy should be permitted to supplement its original answer so as to reflect the current facts of the case, i.e., that two additional ANDAs directed to the same drug product as in the original ANDA (but in different packaging forms) were filed in summer, 2007, disclosed to Merck shortly thereafter, and discovery has proceeded on them since that time. *See* Paragraphs 10, 12, 14, 15 and 27.

"[T]he court may permit the party to serve a supplemental pleading setting forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented." Fed. R. Civ. P. 15(d). The grant of an application under Rule 15(d) is within the sound discretion of the Court. Leave to supplement should be granted if it will promote the just disposition of the case, will not cause undue prejudice or delay and will not prejudice the rights of any parties. See *Medeva Pharma Ltd. v. Am. Home Prods. Corp.,* 201 F.R.D. 103 (D. Del. 2001), citing *The Proctor & Gamble Company v. McNeil-PPC, Inc.* 1998 WL 1745118 (D. Del. December 7, 1998) (internal citations omitted). The Court has broad discretion in the application of the Rule and should apply the Rule in a manner securing "the just, speedy and inexpensive determination of every action." See *Medeva* (citing Fed. R. Civ. P. 1.). Therefore, unless the court finds "undue delay, bad faith or dilatory motive on the part of the movant or undue prejudice to the opposing party an appropriate exercise of a court's discretion

should result in affording a plaintiff the opportunity to test its claim on the merits." *Id.* (internal quotations omitted).[1]

Here, Ranbaxy proposes to add the simple facts that three ANDAs and corresponding products have been at issue in this litigation since last summer. All three ANDAs are directed to the same drug product -- a cilastatin/imipenem combination product, in the same dosage forms. The packaging of each proposed injectable product differs from ANDA to ANDA, but no such differences affect any infringement issue in the case. Moreover, Ranbaxy's invalidity defenses remain as set forth in its original answer and counterclaims and are unaffected by the additional facts proposed to be added to the answer. There is clearly no prejudice to Merck, since its original complaint included all such products within its scope, Merck served discovery requests encompassing all of these proposed injectable products, Ranbaxy provided discovery on all of its proposed injectable products and the litigation has been proceeding based on all three ANDAs and products encompassed thereby since at least September, 2007.

Under these circumstances, the supplementation should be granted since it will promote the just disposition of the case. There has been no undue delay since the supplemental facts are presented within the time set by the Court for amending the pleadings.

[1] In *Medeva,* the court noted that the standard applicable to motions to amend under Fed. R. Civ. P. 15(d) is essentially the same standard that applies to Fed. R. Civ. P. 15(a). (internal citations omitted).

III. CONCLUSION.

For the foregoing reasons, Ranbaxy's Motion for Leave to File an Amended and Supplemental Answer and Counterclaims should be allowed.

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CERTIFICATION PURSUANT TO LOCAL RULE 7.1.1

The undersigned hereby certifies that counsel for Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively, "Ranbaxy") has conferred with counsel for Plaintiff Merck & Co., Inc. ("Merck") regarding the attached motion. Merck does not object to Ranbaxy's amendments to add the Eighth Affirmative Defense and Counterclaim IV alleging inequitable conduct. With respect to the supplementation of Ranbaxy's Answer, Merck's counsel advised that it had not had an opportunity to consult with Merck and, therefore, could not provide Merck's position with respect to the supplementation.

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UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 11, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF and caused the same to be served on the defendant at the addresses and in the manner indicated below:

E-MAIL:

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I hereby certify that on January 11, 2008, the foregoing document was sent to the following non-registered participants in the manner indicated:

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FIRST AMENDED AND SUPPLEMENTAL ANSWER AND COUNTERCLAIMS OF DEFENDANTS RANBAXY INC. AND RANBAXY LABORATORIES LIMITED

Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy") hereby files its First Amended and Supplemental Answer and Counterclaims to the Complaint for Patent Infringement of Plaintiff Merck & Co., Inc. ("Merck") as follows:

PARTIES

1. Ranbaxy admits the allegations of paragraph 1 of the Complaint.

2. Ranbaxy admits that Ranbaxy Inc. is a corporation organized and existing under the laws of the state of Delaware, has a principal place of business at 600 College Road East, Princeton, New Jersey, 08540, and conducts business in the state of Delaware. Ranbaxy admits that Ranbaxy Pharmaceuticals Inc. is engaged in the marketing and sale of pharmaceutical products in the United States and that it conducts business in the state of Delaware. Ranbaxy denies all other allegations in Paragraph 2 of the Complaint.

3. Ranbaxy admits that Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, having a principal place of business at Gurgaon (Haryana) India. Ranbaxy admits that Ranbaxy Inc. is a wholly owned subsidiary of Ranbaxy Laboratories Limited. Ranbaxy Laboratories Limited develops manufactures, markets and sells drug products in India and, in cooperation with Ranbaxy Inc. and Ranbaxy Pharmaceuticals Inc., conducts business in the United States and in the state of Delaware. Ranbaxy denies all other allegations in Paragraph 3 of the Complaint.

4. Ranbaxy admits that Ranbaxy Inc. and Ranbaxy Laboratories Limited have submitted an Abbreviated New Drug Application ("ANDA") directed to imipenem/cilastatin sodium, and associated drug master file(s) seeking approval to engage in the commercial manufacture, use, offer for sale and sale of injectable products comprising imipenem and cilastatin sodium. Ranbaxy denies all other allegations in Paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Paragraph 5 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that this action for patent infringement arises under the patent laws of the United States, and for declaratory relief under 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States. Ranbaxy admits that this Court has jurisdiction over the subject matter of

Merck's infringement counts pursuant to 28 U.S.C. §§ 1331 and 1338(a) and Merck's declaratory judgment counts pursuant 28 U.S.C. §§ 2201 and 2202.

6. Paragraph 6 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy admits that venue is proper in this District for this action only.

MERCK'S PATENT

7. Ranbaxy admits that U.S. Patent No. 5,147,868 ("'868 patent") is entitled "Thienamycin Renal Peptidase Inhibitors," bears an issue date from the United States Patent and Trademark Office of September 15, 1992, lists Merck & Co., Inc. as the assignee, and lists as inventors Donald W. Graham, Edward F. Rogers and Frederick M. Kahan. As presently understood, Ranbaxy also admits that one or more claims of the '868 patent appear to cover the compounds cilastatin and cilastatin sodium. Ranbaxy lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7 of the Complaint and therefore denies the same.

8. Based on Merck's representations, Ranbaxy admits the allegations of paragraph 8 of the Complaint.

9. Ranbaxy is without knowledge sufficient to form a belief in the truth of the allegations of Paragraph 9 of the Complaint, and therefore denies the same.

DEFENDANTS' ACTIONS

10. Ranbaxy admits that it filed an ANDA and associated drug master file(s), seeking approval to engage in the commercial manufacture, use and sale of injectable products comprising imipenem and cilastatin sodium ("proposed injectable products"). The first ANDA was filed before the Complaint, and in summer, 2007, Ranbaxy filed two additional ANDAs for the same proposed injectable products comprising imipenem and cilastatin sodium, in the same dosages, for the same use as injections, as the original ANDA and since that time discovery has been proceeding on all three ANDAs and

proposed injectable products. The subsequently filed ANDAs were prepared based on different packaging of the proposed injectable products. Ranbaxy denies the remaining allegations of Paragraph 10 of the Complaint.

11. Ranbaxy admits that by letter of January 22, 2007, it notified Merck of its ANDA filing; that its proposed injectable products would not infringe any valid claim of the '868 patent, and that Ranbaxy planned to begin marketing its proposed injectable products immediately upon approval. Ranbaxy admits that it requested from Merck a Covenant Not to Sue, which Merck denied. Ranbaxy denies the remaining allegations of Paragraph 11 of the Complaint.

12. Ranbaxy admits that it has complied with the applicable regulatory requirements in filing its ANDAs, and that it has developed and carried out testing on the proposed injectable products that it has developed. Ranbaxy Laboratories Limited manufactures a composition containing imipenem and cilastatin sodium in India and markets and sells that composition in India and Peru. Ranbaxy admits that it is prepared to import its proposed injectable products into the United States and that it has the capacity to manufacture and market its proposed injectable products immediately upon approval of its ANDAs. Ranbaxy denies the remaining allegations of Paragraph 12 of the Complaint.

COUNT 1- DECLARATORY JUDGMENT

13. Ranbaxy repeats and realleges its responses to the allegations in paragraphs 1-12 of the Complaint as though fully set forth herein.

14. Ranbaxy admits engaging in activities in preparation for approval of its ANDAs, but denies that the manufacture, use, offer for sale of sale of its proposed injectable products would constitute infringement of the '868 patent.

15. To the extent the allegations of Paragraph 15 of the Complaint are understood, Ranbaxy admits that it continues to seek FDA approval of its ANDAs, that it

plans to market its proposed injectable products immediately upon FDA approval of its ANDAs, and that it notified Merck of its good-faith belief as to why no valid claim of the '868 would be infringed by Ranbaxy's manufacture, use, offer for sale and sale of its propose injectable products. Ranbaxy denies the remaining allegations of Paragraph 15 of the Complaint.

16. Ranbaxy denies the allegations of Paragraph 16 of the Complaint.

17. By reason of Ranbaxy's having filed its ANDA, Merck's refusal to grant Ranbaxy a covenant not sue, and Merck's having filed suit against Ranbaxy, Ranbaxy admits that an actual controversy exists between Merck and Ranbaxy with respect to the noninfringement, invalidity and unenforceability of the '868 patent.

18. Ranbaxy denies the allegations of Paragraph 18 of the Complaint.

19. Ranbaxy denies the allegations of Paragraph 19 of the Complaint.

20. Ranbaxy denies the allegations of Paragraph 20 of the Complaint.

21. Ranbaxy admits that, through its own investigation, it has learned of the '868 patent but denies the remaining allegations of Paragraph 21 that of the Complaint.

22. Ranbaxy denies the allegations of Paragraph 22 of the Complaint.

23. Ranbaxy denies the allegations of Paragraph 23 of the Complaint.

24. Ranbaxy denies the allegations of Paragraph 24 of the Complaint.

COUNT II -- PATENT INFRINGEMENT

25. Ranbaxy repeats and realleges its responses to the allegations in paragraphs 1-24 of the Complaint as though fully set forth herein.

26. Ranbaxy admits that it has filed an ANDA under Section 505(j) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §355(j) for its proposed injectable products. Ranbaxy denies the remaining allegations of Paragraph 26 of the Complaint.

27. Ranbaxy admits that it seeks approval of its ANDAs and the proposed injectable products described therein, but denies that its proposed injectable products

would infringe any valid claim of the '868 patent. Ranbaxy denies the remaining allegations of Paragraph 27 of the Complaint.

28. Ranbaxy denies the allegations of Paragraph 28 of the Complaint.

29. Ranbaxy denies the allegations of Paragraph 29 of the Complaint.

30. Ranbaxy admits that, through its own investigation, it has learned of the '868 patent but denies the remaining allegations of Paragraph 30 of the Complaint.

31. Ranbaxy denies the allegations of Paragraph 31 of the Complaint.

32. Ranbaxy denies the allegations of Paragraph 32 of the Complaint.

33. Ranbaxy denies the allegations of Paragraph 33 of the Complaint.

MERCK'S PRAYER FOR RELIEF

Ranbaxy denies that Merck is entitled to any aspect of the judgment it seeks.

DEFENSES

Ranbaxy asserts the following defenses, reserving the right to supplement or amend these defenses as discovery proceeds.

FIRST DEFENSE

(Non-infringement of '868 Patent)

34. Ranbaxy does not infringe, has not infringed, and does not and has not induced infringement or contributed to infringement of the '868 patent-in-suit, either literally or under the doctrine of equivalents.

SECOND DEFENSE

(Estoppel/Disclaimer of Claim Scope)

35. Merck is estopped from asserting any scope for one or more of the claims of the '868 patent which would cover Ranbaxy's proposed injectable products because of

amendments, representations, assertions, disclaimers and/or admissions made during the course of proceedings in the United States Patent and Trademark Office ("PTO") during prosecution of the applications leading to the issuance of the '868 patent and during the prosecution of all applications in the family beginning with the filing of Application Serial No. 05/927,213 and other Merck patents/applications and foreign counterparts of any such applications or patents, including but not limited to, prosecution disclaimer.

THIRD DEFENSE

(Estoppel)

36. To the extent not encompassed by Ranbaxy's Second Defense, Merck is estopped from construing the claims of the '868 patent to cover and include Ranbaxy's proposed injectable product.

FOURTH DEFENSE

(Invalidity of '868 Patent)

37. Each and every claim of the '868 patent is invalid for failure to meet the statutory requirements of Title 35 of the United States Code, including, but not limited to, the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

FIFTH DEFENSE

(Invalidity of '868 Patent)

38. Each and every claim of the '868 patent is invalid for failing to meet judicially-created requirements for patentability and enforceability of patents, including but not limited to, obviousness-type double patenting based on U.S. Patent No. 4,539,208.

SIXTH DEFENSE

(Prosecution Laches)

39. Merck's claim for patent infringement and prayers for relief are barred, in whole or in part, because the equitable doctrine of prosecution laches renders the '868 patent unenforceable.

SEVENTH DEFENSE

(Limitation on Damages)

40. Merck is barred under 35 U.S.C. § 287 from recovering damages for any alleged act of infringement by Ranbaxy that occurred prior to actual notice of alleged infringement of the '868 patent from Merck.

EIGHTH DEFENSE

(Inequitable Conduct)

41. The '868 patent is unenforceable due to inequitable conduct in its prosecution before the United States Patent and Trademark Office (the "PTO") as more particularly alleged below.

42. The '868 patent issued on September 15, 1992, from U.S. Patent Application Ser. No. 839,725, filed on February 19, 1992 ("'725 application").

43. The '725 application was a continuation of U.S. Patent Application Ser. No. 07/641,317, filed on January 14, 1991, which was a continuation of U.S. Patent Application Ser. No. 07/244,527, filed on September 9, 1988, which was a continuation of U.S. Patent Application Ser. No. 06/878,391, filed on June 19, 1986, which was a continuation of U.S. Patent Application Ser. No. 06/748,300, filed on June 24, 1985, which was a continuation of U.S. Patent Application Ser. No. 06/465,577, filed on February 10, 1983 (collectively the "'868 patent benefit applications").

44. Continuously during the pendency of each of these applications leading to the '868 patent, from February 10, 1983 until September 15, 1992, Merck, each of the inventors named in the '868 patent, each attorney involved in preparation or prosecution of each application, and every other person who was substantively involved in the

preparation or prosecution of the application and who was associated with the inventor, with the assignee or with anyone to whom there was an obligation to assign the application, had a duty to disclose to the PTO all information known to the person to be material to examination of each of the applications.

45. During prosecution of the '868 patent benefit applications, Merck, its prosecuting attorneys, and one or more of the inventors named in the '868 patent violated the duty of disclosure by withholding from the PTO information that was highly material to examination of each of the applications leading to the '868 patent, including copending applications claiming closely-related subject matter and issued patents claiming closely-related subject matter, that a reasonable examiner would have considered highly important in deciding whether to allow any claim of the '868 patent to issue.

46. The highly material information that Merck withheld from the examiners responsible for examining the '725 application and the '868 patent benefit applications included applications and patents claiming combinations of dipeptidase inhibitor compounds as claimed in the '868 patent with thienamycin-type antibiotic compounds. These highly material copending U.S. patent applications and issued U.S. Patents include U.S. Patent No. 4,539,208 (expired) ("'208 patent"), U.S. Patent Application Ser. No. 06/291,711, filed August 10, 1981, U.S. Patent 4,880,793 (expired) ("'793 patent"), U.S. Patent Application Ser. No. 06/340,152, filed January 18, 1982, U.S. Patent Application Ser. No. 06/394,311, filed July 7, 1982, U.S. Patent Application Ser. No. 06/840,532, filed March 14, 1986, U.S. Patent 5,071,843 ("'843 patent"), U.S. Patent Application Ser. No. 06/605,343, filed April 30, 1984, U.S. Patent Application Ser. No. 06/880,339, filed June 25, 1986, U.S. Patent Application Ser. No. 07/384,845, filed July 24, 1989, U.S. Patent Application Ser. No. 07/741,678, filed January 25, 1990, and U.S. Patent Application Ser. No. 07/671,486 (collectively the "combination applications" and "combination patents").

47. Additional highly material information Merck withheld from the examiners responsible for examining the '725 application and the '868 patent benefit applications included applications and patents claiming methods of using dipeptidase inhibitor compounds as claimed in the '868 patent. These highly material patents and applications included U.S. Patent 4,616,038 ("'038 patent"), U.S. Patent Application Ser. No. 06/340,152, filed January 18, 1982, and U.S. Patent Application Ser. No. 06/747,750, filed January 24, 1985 (collectively the "dipeptidase inhibitor method applications").

48. Claim 1 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 1 of the '208 patent. Specifically, Claim 1 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

49. Claim 7 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 7 of the '208 patent. Specifically, Claim 7 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

50. Claim 8 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 8 of the '208 patent. Specifically, Claim 8 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which

anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

51. Claim 9 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 9 of the '208 patent. Specifically, Claim 9 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

52. Claim 10 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 10 of the '208 patent. Specifically, Claim 10 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

53. Claim 11 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 11 of the '208 patent. Specifically, Claim 11 of the '208 patent recites a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

54. Claim 24 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims

1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 24 of the '208 patent. Specifically, Claim 24 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

55. Claim 29 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 29 of the '208 patent. Specifically, Claim 29 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method claimed in Claim 24 of the '868 patent.

56. Claims 30 and 33 of the '208 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claims 30 and 33 of the '208 patent. Specifically, Claims 30 and 33 of the '208 patent claim a method of treatment using a combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method claimed in Claim 24 of the '868 patent.

57. Claim 32 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 32 of the '208 patent. Specifically, Claim 32 of the '208

patent claims a method of treatment using the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method claimed in Claim 24 of the '868 patent.

58. Claim 34 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 34 of the '208 patent. Specifically, Claim 34 of the '208 patent claims a method of treatment using the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method claimed in Claim 24 of the '868 patent.

59. Claims 1, 7, 8, 9, 10, 11, 24, 29, 30, 32, 33 and 34 of the '208 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 7, 8, 9, 10, 11, 24, 29, 30, 32, 33 and 34 of the '208 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '208 patent and the '868 patent name different inventive entities, and the claims of the '208 patent were material because a reasonable examiner would have considered them important in deciding whether the claims of the '868 patent were barred by 35 U.S.C. §135(b).

60. Claims 1, 7, 8, 9, 10, 11, 24, 29, 30, 32, 33 and 34 of the '208 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 7, 8, 9, 10, 11, 24, 29, 30, 32, 33 and 34 of the '208 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '208 patent and the '868 patent name different inventive entities, and the claims of the '208 patent were material because

a reasonable examiner would have considered them important in deciding whether to require an interference before allowing the claims of the '868 patent to issue.

61. U.S. Patent Application Ser. No. 06/291,711 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/465,577, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 465,577 to issue.

62. U.S. Patent Application Ser. No. 06/291,711 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/748,300, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 465,577 to issue.

63. Claim 1 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 1 of the '038 patent. Specifically, Claim 1 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

64. Claim 2 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 2 of the '038 patent. Specifically, Claim 2 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

65. Claim 3 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 3 of the '038 patent. Specifically, Claim 3 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

66. Claim 4 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 4 of the '038 patent. Specifically, Claim 4 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

67. Claim 5 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 5 of the '038 patent. Specifically, Claim 5 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

68. Claim 6 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 5 of the '038 patent. Specifically, Claim 6 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the

compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

69. Claims 1 to 6 of the '038 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1 to 6 of the '038 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '038 patent and the '868 patent name different inventive entities, and the claims of the '038 patent were material because a reasonable examiner would have considered them important in deciding whether the claims of the '868 patent were barred by 35 U.S.C. §135(b).

70. Claims 1 to 6 of the '038 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1 to 6 of the '038 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '038 patent and the '868 patent name different inventive entities, and the claims of the '038 patent were material because a reasonable examiner would have considered them important in deciding whether to require an interference before allowing the claims of the '868 patent to issue.

71. U.S. Patent Application Ser. No. 06/340,152 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/465,577, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/465,577 to issue.

72. U.S. Patent Application Ser. No. 06/747,750 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/748,300, because a reasonable examiner would have considered patentably indistinct claims of the two

copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/748,300 to issue.

73. U.S. Patent Application Ser. No. 06/747,750 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/878,391, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/878,391 to issue.

74. Claims 1 to 6 of the '038 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1 to 6 of the '038 patent define subject matter that is patentably indistinct from Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '038 patent and the '868 patent name different inventive entities, and the claims of the '038 patent were material because a reasonable examiner would have considered them important in deciding whether to allow the claims of the '868 patent to issue.

75. Claim 1 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 1 of the '793 patent. Specifically, Claim 1 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

76. Claim 2 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 2 of the '793 patent. Specifically, Claim 2 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes

obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

77. Claim 7 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 7 of the '793 patent. Specifically, Claim 7 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '793 patent, and the method recited in Claim 24 of the '793 patent.

78. Claim 8 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 8 of the '793 patent. Specifically, Claim 8 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '793 patent, and the method recited in Claim 24 of the '868 patent.

79. Claim 9 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 9 of the '793 patent. Specifically, Claim 9 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

80. Claim 10 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double

patenting in view of Claim 10 of the '793 patent. Specifically, Claim 10 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

81. Claim 11 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 11 of the '793 patent. Specifically, Claim 11 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

82. Claim 24 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 24 of the '793 patent. Specifically, Claim 24 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

83. Claim 29 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 29 of the '793 patent. Specifically, Claim 29 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

84. Claim 31 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 31 of the '793 patent. Specifically, Claim 31 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

85. Claims 1, 2, 7, 8, 9, 10, 11, 24, 29, and 31 of the '793 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 7, 8, 9, 10, 11, 24, 29, and 31 of the '793 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '793 patent and the '868 patent name different inventive entities, and the claims of the '793 patent were material because a reasonable examiner would have considered them important in deciding whether the claims of the '868 patent were barred by 35 U.S.C. §135(b).

86. Claims 1, 2, 7, 8, 9, 10, 11, 24, 29, and 31 of the '793 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 Patent, because Claims 1, 2, 7, 8, 9, 10, 11, 24, 29, and 31 of the '793 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '793 patent and the '868 patent name different inventive entities, and the claims of the '793 patent were material because a reasonable examiner would have considered them important in deciding whether to require an interference before allowing the claims of the '868 patent to issue.

87. U.S. Patent Application Ser. No. 06/394,311 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/465,577, because a reasonable examiner would have considered patentably indistinct claims of the two

copending applications to be important in deciding whether to allow any claim of Application Ser. No. 465,577 to issue.

88. U.S. Patent Application Ser. No. 06/394,311 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/748,300, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/748,300 to issue.

89. U.S. Patent Application Ser. No. 06/840,532 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/878,391, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/878,391 to issue.

90. U.S. Patent Application Ser. No. 06/840,532 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/244,527, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/244,527 to issue.

91. Claim 1 of the '843 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 1 of the '843 patent. Specifically, Claim 1 of the '843 patent claims a composition containing a carbapenem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

92. Claim 2 of the '843 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20,

22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 2 of the '843 patent. Specifically, Claim 2 of the '843 patent claims a composition containing a carbapenem and a dipeptidase inhibitor and a carrier, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

93. Claim 5 of the '843 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 Patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 5 of the '843 patent. Specifically, Claim 5 of the '843 patent claims a composition containing a carbapenem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

94. Claims 1, 2, and 5 of the '843 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2 and 5 of the '843 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '843 patent and the '868 patent name different inventive entities, and the claims of the '843 patent were material because a reasonable examiner would have considered them important in deciding whether to require an interference before allowing the claims of the '868 patent to issue.

95. U.S. Patent Application Ser. No. 06/340,152 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/465,577, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/465,577 to issue.

96. U.S. Patent Application Ser. No. 06/605,343 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/748,300, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/748,300 to issue.

97. U.S. Patent Application Ser. No. 06/880,339 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/878,391, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/878,391 to issue.

98. U.S. Patent Application Ser. No. 06/880,339 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/244,527, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/244,527 to issue.

99. U.S. Patent Application Ser. No. 07/384,845 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/244,527, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/244,527 to issue.

100. U.S. Patent Application Ser. No. 07/471,678 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/244,527, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/244,527 to issue.

101. U.S. Patent Application Ser. No. 07/471,678 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/641,317, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/641,317 to issue.

102. U.S. Patent Application Ser. No. 07/681,486 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/839,725, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/839,725 to issue.

103. On information and belief, Merck, its attorneys, and one or more of the inventors named in the '868 patent intentionally concealed the existence of the '208 patent, the '038 patent, the '793 patent, the '843 patent, the combination applications, and dipeptidase inhibitor method applications identified above from the examiners responsible for examining the '868 patent application and '868 patent benefit applications, with knowledge that these patents and applications were material to examination, and with intent to deceive the examiners responsible for examining the '868 patent application and the '868 patent benefit applications, as more specifically alleged below.

104 Merck attorneys Daniel T. Szura and Robert J. North were each involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/465,577 and U.S. Patent Application Ser. No. 06/291,711. On information and belief, each of these attorneys was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/340,152 to examination of Ser. No. 06/465,577. On information and belief, Daniel T. Szura and Robert J. North concealed the existence of

Ser. No. 06/340,152 from the examiner responsible for examination of Ser. No. 06/465,577, with intent to deceive the PTO.

105. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/748,300 and U.S. Patent Application Ser. No. 06/291,711. On information and belief, Robert J. North was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/291,711 to examination of Ser. No. 06/748,300. On information and belief, Robert J. North concealed the existence of Ser. No. 06/291,711 from the examiner responsible for examination of Ser. No. 06/748,300, with intent to deceive the PTO.

106. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/291,711, which issued as the '208 patent. On information and belief, Robert J. North was aware of the '208 patent and was aware of the materiality of the '208 patent to examination of Ser. No. 06/748,300. On information and belief, Robert J. North concealed the allowance and existence of the '208 patent from the examiner responsible for examination of Ser. No. 06/748,300, with intent to deceive the PTO.

107. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/291,711 which issued as the '208 patent. On information and belief, Robert J. North was aware of the '208 patent and was aware of the materiality of the '208 patent to examination of Ser. No. 06/878,391. On information and belief, Robert J. North concealed the allowance and existence of the '208 patent from the examiner responsible for examination of Ser. No. 06/878,391, with intent to deceive the PTO.

108. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/291,711 which issued as the '208 patent. On information and belief, Robert J. North was aware of the '208 patent and was aware of

the materiality of the '208 patent to examination of Ser. No. 07/244,527. On information and belief, Robert J. North concealed the allowance and existence of the '208 patent from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

109. Merck attorneys Daniel T. Szura, Raymond M. Speer, and Robert J. North were each involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/465,577 and U.S. Patent Application Ser. No. 06/340,152. On information and belief, each of these attorneys was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/340,152 to examination of Ser. No. 06/465,577. On information and belief, Daniel T. Szura, Raymond M. Speer, and Robert J. North each concealed the existence of Ser. No. 06/340,152 from the examiner responsible for examination of Ser. No. 06/465,577, with intent to deceive the PTO.

110. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/747,750 and U.S. Patent Application Ser. No. 06/748,300. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/747,750 to examination of Ser. No. 06/748,300. On information and belief, Robert J. North concealed the existence of Ser. No. 06/747,750 from the examiner responsible for examination of Ser. No. 06/748,300, with intent to deceive the PTO.

111. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/747,750 and U.S. Patent Application Ser. No. 06/878,391. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/747,750 to examination of Ser. No. 06/878,391. On information and belief, Robert J. North concealed the existence of Ser. No. 06/747,750 from the examiner responsible for examination of Ser. No. 06/878,391, with intent to deceive the PTO.

112. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/747,750, which issued as the '038 patent. On information and belief, Robert J. North was aware of the '038 patent and was aware of the materiality of the '038 patent to examination of Ser. No. 06/878,391. On information and belief, Robert J. North concealed the allowance and existence of the '038 patent from the examiner responsible for examination of Ser. No. 06/878,391, with intent to deceive the PTO.

113. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/747,750, which issued as the '038 patent. On information and belief, Robert J. North was aware of the '038 patent and was aware of the materiality of the '038 patent to examination of Ser. No. 07/244,527. On information and belief, Robert J. North concealed the allowance and existence of the '038 patent from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

114. Merck attorneys Daniel T. Szura, Raymond M. Speer, and Robert J. North were each involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/465,577 and U.S. Patent Application Ser. No. 06/394,311. On information and belief, each of these attorneys was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/394,311 to examination of Ser. No. 06/465,577. On information and belief, Daniel T. Szura, Raymond M. Speer, and Robert J. North each concealed the existence of Ser. No. 06/394,311 from the examiner responsible for examination of Ser. No. 06/465,577, with intent to deceive the PTO.

115. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/394,311 and U.S. Patent Application Ser. No. 06/748,300. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No.

06/394,311 to examination of Ser. No. 06/748,300. On information and belief, Robert J. North concealed the existence of Ser. No. 06/394,311 from the examiner responsible for examination of Ser. No. 06/748,300, with intent to deceive the PTO.

116. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/840,532 and U.S. Patent Application Ser. No. 06/878,391. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/840,532 to examination of Ser. No. 06/878,391. On information and belief, Robert J. North concealed the existence of Ser. No. 06/840,532 from the examiner responsible for examination of Ser. No. 06/878,391, with intent to deceive the PTO.

117. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/840,532 and U.S. Patent Application Ser. No. 07/244,527. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/840,532 to examination of Ser. No. 07/244,527. On information and belief, Robert J. North concealed the existence of Ser. No. 06/840,532 from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

118. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/840,532, which issued as the '793 patent, and U.S. Patent Application Ser. No. 07/244,527. On information and belief, Robert J. North was aware of the '793 patent and was aware of the materiality of the '793 patent to examination of Ser. No. 07/244,527. On information and belief, Robert J. North concealed the allowance and existence of the '793 patent from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

119. Merck attorneys Daniel T. Szura, Raymond M. Speer, and Robert J. North were each involved in preparation or prosecution of U.S. Patent Application Ser. No.

06/465,577 and U.S. Patent Application Ser. No. 06/340,152. On information and belief, each of these attorneys was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/340,152 to examination of Ser. No. 06/465,577. On information and belief, Daniel T. Szura, Raymond M. Speer, and Robert J. North each concealed the existence of Ser. No. 06/340,152 from the examiner responsible for examination of Ser. No. 06/465,577, with intent to deceive the PTO.

120. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/605,343 and U.S. Patent Application Ser. No. 06/748,300. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/605,343 to examination of Ser. No. 06/748,300. On information and belief, Robert J. North concealed the existence of Ser. No. 06/605,343 from the examiner responsible for examination of Ser. No. 06/748,300, with intent to deceive the PTO.

121. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/880,339 and U.S. Patent Application Ser. No. 06/878,391. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/880,339 to examination of Ser. No. 06/878,391. On information and belief, Robert J. North concealed the existence of Ser. No. 06/880,339 from the examiner responsible for examination of Ser. No. 06/878,391, with intent to deceive the PTO.

122. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/880,339 and U.S. Patent Application Ser. No. 07/244,527. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/880,339 to examination of Ser. No. 07/244,527. On information and belief, Robert J.

North concealed the existence of Ser. No. 06/880,339 from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

123. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/384,845 and U.S. Patent Application Ser. No. 07/244,527. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 07/384,845 to examination of Ser. No. 07/244,527. On information and belief, Robert J. North concealed the existence of Ser. No. 07/384,845 from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

124. Merck attorneys Robert J. North and Frank P. Grassler were involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/471,678 and U.S. Patent Application Ser. No. 07/244,527. On information and belief, Robert J. North and Frank P. Grassler were aware of both applications and were aware of the materiality of information including the claims of Ser. No. 07/471,678 to examination of Ser. No. 07/244,527. On information and belief, Robert J. North and Frank P. Grassler concealed the existence of Ser. No. 07/471,678 from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

125. Merck attorney Frank P. Grassler was involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/471,678 and U.S. Patent Application Ser. No. 07/641,317. On information and belief, Frank P. Grassler was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 07/471,678 to examination of Ser. No. 07/641,317. On information and belief, Frank P. Grassler concealed the existence of Ser. No. 07/471,678 from the examiner responsible for examination of Ser. No. 07/641,317, with intent to deceive the PTO.

126. Merck attorney Frank P. Grassler was involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/681,486 and U.S. Patent Application

Ser. No. 07/839,725. On information and belief, Frank P. Grassler was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 07/681,486 to examination of Ser. No. 07/839,725. On information and belief, Frank P. Grassler concealed the existence of Ser. No. 07/681,486 from the examiner responsible for examination of Ser. No. 07/839,725, with intent to deceive the PTO.

127. Merck attorney Frank P. Grassler was involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/681,486, which issued as the '843 patent, and U.S. Patent Application Ser. No. 07/641,317. On information and belief, Frank P. Grassler was aware of the '843 patent and was aware of the materiality of the '843 patent to examination of Ser. No. 07/641,317. On information and belief, Frank P. Grassler concealed the allowance and existence of the '843 patent from the examiner responsible for examination of Ser. No. 07/641,317, with intent to deceive the PTO.

128. Merck attorney Frank P. Grassler was involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/681,486, which issued as the '843 patent, and U.S. Patent Application Ser. No. 07/839,725. On information and belief, Frank P. Grassler was aware of the '843 patent and was aware of the materiality of the '843 patent to examination of Ser. No. 07/839,725. On information and belief, Frank P. Grassler concealed the allowance and existence of the '843 patent from the examiner responsible for examination of Ser. No. 07/839,725, with intent to deceive the PTO.

129. The '868 patent is unenforceable because Merck and its attorneys including at least Daniel T. Szura, Raymond M. Speer, Robert J. North, and Frank P. Grassler violated their duty of good faith in dealing with the PTO under 37 C.F.R. §1.56, by failing to disclose the '208 patent, the '038 patent, the '793 patent and the '843 patent and the applications leading to issuance of these patents to the examiners responsible for examining the '868 patent application and the '868 benefit applications, as alleged more fully above. On information and belief, Merck and its attorneys intentionally concealed

the existence of the '208 patent, the '038 patent, the '793 patent and the '843 patent and the applications leading to issuance of these patents, from the examiners responsible for examining the '868 patent application and the '868 benefit applications, with intent to deceive the PTO.

RANBAXY'S COUNTERCLAIMS

Defendants/Counterclaimants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy") hereby allege the following counterclaims against Plaintiff/Counterdefendant Merck & Co., Inc. ("Merck"), for declaratory judgment that U.S. Patent No. 5,147,868 ("'868 patent") is invalid, unenforceable, and/or not infringed by the proposed injectable products comprising imipenem and cilastatin sodium ("proposed injectable product") in Ranbaxy's Abbreviated New Drug Application ("ANDA") and associated drug master file(s).

PARTIES, JURISDICTION AND VENUE

130. Ranbaxy Inc. is a corporation organized and existing under the laws of the state of Delaware, and has a principal place of business at 600 College Road East, Princeton, New Jersey, 08540. Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, having a principal place of business in Gurgaon (Haryana) India.

131. On information and belief, Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey.

132. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367(a), 2201 and 2202, and 35 U.S.C. § 1, *et seq.*

133. Merck has submitted to the personal jurisdiction of this Court.

134. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400 and because this suit was filed in this district by Merck.

THE CONTROVERSY

135. This is an action based on an actual controversy between Ranbaxy and Merck concerning the invalidity and/or noninfringement of the '868 patent-in-suit, and Ranbaxy's right to continue to seek approval of its ANDA for its proposed injectable products, and upon approval by the FDA, to manufacture use, sell and offer to sell and import into the United States its proposed injectable products.

136. The '868 patent is entitled "Thienamycin Renal Peptidase Inhibitors," bears an issue date from the United States Patent and Trademark Office of September 15, 1992, lists Merck & Co., Inc. as the assignee, and lists as inventors Donald W. Graham, Edward F. Rogers and Frederick M. Kahan.

137. Merck has represented that one or more claims of the '868 patent appear to cover the compounds cilastatin and cilastatin sodium. Merck has represented that it currently sells PRIMAXIN® I.M., which is an injectable suspension containing imipenem and cilastatin sodium, and PRIMAXIN® I.V., which is an injection containing imipenem and cilastatin sodium.

138. Ranbaxy has submitted, and is continuing to seek FDA approval of, anANDA directed to products containing imipenem/cilastatin sodium, and approval to engage in the commercial manufacture, use, offer for sale, sale, and importation into the United States, its proposed injectable products under that ANDA, which Merck alleges infringes the '868 patent-in-suit.

139. By letter of January 22, 2007, Ranbaxy informed Merck that it had submitted to FDA its ANDA directed to its proposed injectable product, and stated that the manufacture, use, offer for sale or sale of its proposed injectable products would not infringe any valid claim of Merck's '868 patent.

140. Ranbaxy also informed Merck that it planned to begin marketing of its proposed injectable products immediately upon FDA approval of its ANDA. Ranbaxy sought from Merck a covenant not to sue on the '868 patent, and provided to Merck an offer of confidential access to its ANDA and its DMF(s) for the purpose of determining whether to grant Ranbaxy a covenant not to sue. Merck did not covenant not to sue Ranbaxy, and filed this suit April 30, 2007.

141. Ranbaxy has undertaken substantial efforts in developing and seeking approval for its imipenem/cilastatin proposed injectable products set forth in its ANDA.

142. In view of the foregoing, an actual justiciable controversy exists by virtue of Ranbaxy's notification to Merck of its ANDA filing, Ranbaxy's request for a covenant not to be sued on the '868 patent, and Merck's subsequent filing of the present suit as to Ranbaxy's right to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and importation into the United States, its proposed injectable products described in its ANDA.

COUNTERCLAIM I

(Noninfringement of '868 Patent)

143. Ranbaxy repeats and realleges paragraphs 130-142 above as if fully set forth herein.

144. Ranbaxy has not manufactured, used, sold, or offered for sale in the United States, or imported into the United States, any products that infringe any valid claim of the '868 patent, either literally or under the doctrine of equivalents.

145. Ranbaxy's proposed injectable products do not infringe and does not and has not induced infringement or contributed to infringement of any valid claim of the '868 patent, either literally or under the doctrine of equivalents.

146. Merck is estopped from asserting any scope for one or more of the claims of the '868 patent which would cover Ranbaxy's proposed injectable products because of amendments, representations, assertions, disclaimers and/or admissions made during the course of proceedings in the United States Patent and Trademark Office ("PTO") during prosecution of the applications leading to the issuance of the '868 patent applications and during the prosecution of all applications in the family beginning with the filing of Application Serial No. 05/927,213 and other Merck patents/applications and foreign counterparts of any such applications or patents, including but not limited to, prosecution disclaimer.

COUNTERCLAIM II

(Invalidity of '868 Patent)

147. Ranbaxy repeats and realleges paragraphs 130-146 above as if fully set forth herein.

148. Each and every claim of the '868 patent is invalid for failure to meet the statutory requirements of Title 35 of the United States Code, including, but not limited to, the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

149. Each and every claim of the '868 patent is invalid for failing to meet judicially-created requirements for patentability and enforceability of patents, including but not limited to, obviousness-type double patenting based on U.S. Patent No. 4,539,208.

COUNTERCLAIM III

(Unenforceability)

150. Ranbaxy repeats and realleges paragraphs 130-149 above as if fully set forth herein.

151. Merck unfairly and inequitably filed multiple continuation applications over a long period of time. Because Merck failed to timely prosecute the '868 patent, the '868 patent is unenforceable due to prosecution laches.

COUNTERCLAIM IV

(Unenforceability)

152. Ranbaxy repeats and realleges paragraphs 130-151 above as if fully set forth.

153. The '868 patent is unenforceable due to inequitable conduct by Merck and its attorneys in prosecuting the '868 patent before the United States Patent and Trademark Office as alleged in Ranbaxy's Eighth Defense above (paragraphs 41-129).

154. Ranbaxy therefore seeks and is entitled to a judicial determination that the '868 patent is unenforceable for inequitable conduct before the PTO.

DEMAND FOR JUDGMENT

WHEREFORE, Ranbaxy prays for the following relief:

(1) That any and all relief requested by Merck, as set forth in the Prayer of Relief of the Complaint, be denied and that the Complaint be dismissed with prejudice;

(2) That a judgment be entered declaring that Ranbaxy has not and does not infringe any claim of U.S. Patent No. 5,147,868;

(3) That a judgment be entered declaring all claims of U.S. Patent No. 5,147,868 invalid and/or unenforceable;

(4) That Ranbaxy has a lawful right to seek and obtain FDA approval of its ANDAs for its imipenem/cilastatin sodium injectable products, and that based on the noninfringement, invalidity and/or unenforceability of U.S. Patent No. 5,147,868, Ranbaxy has a right to import, manufacture, use, offer for sale and

sell its proposed imipenem/cilastatin sodium injectable products once approved by FDA;

(5) That Merck, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them, be preliminarily and permanently enjoined from threatening or initiating further infringement litigation against Ranbaxy or any of its customers, dealers or suppliers, or any prospective sellers, dealers, distributors or customers of Ranbaxy, or charging any of them either orally or in writing with infringement of U.S. Patent No. 5,147,868;

(6) That a judgment be entered declaring this case to be exceptional within the meaning of 35 U.S.C. §285 and that Ranbaxy is entitled to recover its reasonable attorneys' fees upon prevailing in this action;

(7) That Ranbaxy be awarded costs, attorneys' fees and other relief, both legal and equitable, to which they may be justly entitled; and

(8) That Ranbaxy be awarded such other relief as this Court deems just and proper.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., Inc. Plaintiff, v. RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Defendant.	C.A. No. 07-229 (GMS)
RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Counterclaim Plaintiff, v. MERCK & CO., Inc. Counterclaim Defendant.	

FIRST AMENDED AND SUPPLEMENTAL ANSWER AND COUNTERCLAIMS OF DEFENDANTS RANBAXY INC. AND RANBAXY LABORATORIES LIMITED

Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy") hereby ~~answer~~files its First Amended and Supplemental Answer and Counterclaims to the Complaint for Patent Infringement of Plaintiff Merck & Co., Inc. ("Merck") as follows:

PARTIES

1. Ranbaxy admits the allegations of paragraph 1 of the Complaint.

2. Ranbaxy admits that Ranbaxy Inc. is a corporation organized and existing under the laws of the state of Delaware, has a principal place of business at 600 College Road East, Princeton, New Jersey, 08540, and conducts business in the state of Delaware. Ranbaxy admits that Ranbaxy Pharmaceuticals Inc. is engaged in the marketing and sale of pharmaceutical products in the United States and that it conducts business in the state of Delaware. Ranbaxy denies all other allegations in Paragraph 2 of the Complaint.

3. Ranbaxy admits that Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, having a principal place of business at Gurgaon (Haryana) India. Ranbaxy admits that Ranbaxy Inc. is a wholly owned subsidiary of Ranbaxy Laboratories Limited. Ranbaxy Laboratories Limited develops manufactures, markets and sells drug products in India and, in cooperation with Ranbaxy Inc. and Ranbaxy Pharmaceuticals Inc., conducts business in the United States and in the state of Delaware. Ranbaxy denies all other allegations in Paragraph 3 of the Complaint.

4. Ranbaxy admits that Ranbaxy Inc. and Ranbaxy Laboratories Limited have submitted an Abbreviated New Drug Application ("ANDA") directed to imipenem/cilastatin sodium, and associated drug master file(s) seeking approval to engage in the commercial manufacture, use, offer for sale and sale of injectable products comprising imipenem and cilastatin sodium. Ranbaxy denies all other allegations in Paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Paragraph 5 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that this action for patent infringement arises under the patent laws of the United States, and for declaratory relief under 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States. Ranbaxy admits that this Court has jurisdiction over the subject matter of Merck's

infringement counts pursuant to 28 U.S.C. §§ 1331 and 1338(a) and Merck's declaratory judgment counts pursuant 28 U.S.C. §§ 2201 and 2202.

6. Paragraph 6 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy admits that venue is proper in this District for this action only.

MERCK'S PATENT

7. Ranbaxy admits that U.S. Patent No. 5,147,868 ("'868 patent") is entitled "Thienamycin Renal Peptidase Inhibitors," bears an issue date from the United States Patent and Trademark Office of September 15, 1992, lists Merck & Co., Inc. as the assignee, and lists as inventors Donald W. Graham, Edward F. Rogers and Frederick M. Kahan. As presently understood, Ranbaxy also admits that one or more claims of the '868 patent appear to cover the compounds cilastatin and cilastatin sodium. Ranbaxy lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7 of the Complaint and therefore denies the same.

8. Based on Merck's representations, Ranbaxy admits the allegations of paragraph 8 of the Complaint.

9. Ranbaxy is without knowledge sufficient to form a belief in the truth of the allegations of Paragraph 9 of the Complaint, and therefore denies the same.

DEFENDANTS' ACTIONS

10. Ranbaxy admits that it filed an ANDA and associated drug master file(s), seeking approval to engage in the commercial manufacture, use and sale of injectable products comprising imipenem and cilastatin sodium ("proposed injectable products"). The first ANDA was filed before the Complaint, and in summer, 2007, Ranbaxy filed two additional ANDAs for the same proposed injectable products comprising imipenem and cilastatin sodium, in the same dosages, for the same use as injections, as the original ANDA and since that time discovery has been proceeding on all three ANDAs and proposed injectable products. The subsequently filed ANDAs were prepared based on

different packaging of the proposed injectable products. Ranbaxy denies the remaining allegations of Paragraph 10 of the Complaint.

11. Ranbaxy admits that by letter of January 22, 2007, it notified Merck of its ANDA filing; that its proposed injectable products would not infringe any valid claim of the '868 patent, and that Ranbaxy planned to begin marketing its proposed injectable products immediately upon approval. Ranbaxy admits that it requested from Merck a Covenant Not to Sue, which Merck denied. Ranbaxy denies the remaining allegations of Paragraph 11 of the Complaint.

12. Ranbaxy admits that it has complied with the applicable regulatory requirements in filing its ~~ANDA~~ANDAs, and that it has developed and carried out testing on the proposed injectable products that it has developed. Ranbaxy Laboratories Limited manufactures a composition containing imipenem and cilastatin sodium in India and markets and sells that composition in India and Peru. Ranbaxy admits that it is prepared to import its proposed injectable products into the United States and that it has the capacity to manufacture and market its proposed injectable products immediately upon approval of its ~~ANDA~~ANDAs. Ranbaxy denies the remaining allegations of Paragraph 12 of the Complaint.

COUNT 1- DECLARATORY JUDGMENT

13. Ranbaxy repeats and realleges its responses to the allegations in paragraphs 1-12 of the Complaint as though fully set forth herein.

14. Ranbaxy admits engaging in activities in preparation for approval of its ~~ANDA~~ANDAs, but denies that the manufacture, use, offer for sale of sale of its proposed injectable products would constitute infringement of the '868 patent.

15. To the extent the allegations of Paragraph 15 of the Complaint are understood, Ranbaxy admits that it continues to seek FDA approval of its ~~ANDA~~ANDAs, that it plans to market its proposed injectable products immediately upon FDA approval of its ~~ANDA~~ANDAs, and that it notified Merck of its good-faith belief as to why no valid

claim of the '868 would be infringed by Ranbaxy's manufacture, use, offer for sale and sale of its propose injectable products. Ranbaxy denies the remaining allegations of Paragraph 15 of the Complaint.

16. Ranbaxy denies the allegations of Paragraph 16 of the Complaint.

17. By reason of Ranbaxy's having filed its ANDA, Merck's refusal to grant Ranbaxy a covenant not sue, and Merck's having filed suit against Ranbaxy, Ranbaxy admits that an actual controversy exists between Merck and Ranbaxy with respect to the noninfringement, invalidity and unenforceability of the '868 patent.

18. Ranbaxy denies the allegations of Paragraph 18 of the Complaint.

19. Ranbaxy denies the allegations of Paragraph 19 of the Complaint.

20. Ranbaxy denies the allegations of Paragraph 20 of the Complaint.

21. Ranbaxy admits that, through its own investigation, it has learned of the '868 patent but denies the remaining allegations of Paragraph 21 that of the Complaint.

22. Ranbaxy denies the allegations of Paragraph 22 of the Complaint.

23. Ranbaxy denies the allegations of Paragraph 23 of the Complaint.

24. Ranbaxy denies the allegations of Paragraph 24 of the Complaint.

COUNT II -- PATENT INFRINGEMENT

25. Ranbaxy repeats and realleges its responses to the allegations in paragraphs 1-24 of the Complaint as though fully set forth herein.

26. Ranbaxy admits that it has filed an ANDA under Section 505(j) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §355(j) for its proposed injectable products. Ranbaxy denies the remaining allegations of Paragraph 26 of the Complaint.

27. Ranbaxy admits that it seeks approval of its ~~ANDA~~ANDAs and the proposed injectable products described therein, but denies that its proposed injectable products would infringe any valid claim of the '868 patent. Ranbaxy denies the remaining allegations of Paragraph 27 of the Complaint.

28. Ranbaxy denies the allegations of Paragraph 28 of the Complaint.

29. Ranbaxy denies the allegations of Paragraph 29 of the Complaint.

30. Ranbaxy admits that, through its own investigation, it has learned of the '868 patent but denies the remaining allegations of Paragraph 30 of the Complaint.

31. Ranbaxy denies the allegations of Paragraph 31 of the Complaint.

32. Ranbaxy denies the allegations of Paragraph 32 of the Complaint.

33. Ranbaxy denies the allegations of Paragraph 33 of the Complaint.

MERCK'S PRAYER FOR RELIEF

Ranbaxy denies that Merck is entitled to any aspect of the judgment it seeks.

DEFENSES

Ranbaxy asserts the following defenses, reserving the right to supplement or amend these defenses as discovery proceeds.

FIRST DEFENSE

(Non-infringement of '868 Patent)

34. Ranbaxy does not infringe, has not infringed, and does not and has not induced infringement or contributed to infringement of the '868 patent-in-suit, either literally or under the doctrine of equivalents.

SECOND DEFENSE

(Estoppel/Disclaimer of Claim Scope)

35. Merck is estopped from asserting any scope for one or more of the claims of the '868 patent which would cover Ranbaxy's proposed injectable products because of amendments, representations, assertions, disclaimers and/or admissions made during the course of proceedings in the United States Patent and Trademark Office ("PTO") during

prosecution of the applications leading to the issuance of the '868 patent ~~("the '868 patent applications")~~ and during the prosecution of all applications in the family beginning with the filing of Application Serial No. 05/927,213 ~~("the '213 family applications")~~ and other Merck patents/applications and foreign counterparts of any such applications or patents, including but not limited to, prosecution disclaimer.

THIRD DEFENSE

(Estoppel)

36. To the extent not encompassed by Ranbaxy's Second Defense, Merck is estopped from construing the claims of the '868 patent to cover and include Ranbaxy's proposed injectable product.

FOURTH DEFENSE

(Invalidity of '868 Patent)

37. Each and every claim of the '868 patent is invalid for failure to meet the statutory requirements of Title 35 of the United States Code, including, but not limited to, the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

FIFTH DEFENSE

(Invalidity of '868 Patent)

38. Each and every claim of the '868 patent is invalid for failing to meet judicially-created requirements for patentability and enforceability of patents, including but not limited to, obviousness-type double patenting based on U.S. Patent No. 4,539,208.

SIXTH DEFENSE

(Prosecution Laches)

39. Merck's claim for patent infringement and prayers for relief are barred, in whole or in part, because the equitable doctrine of prosecution laches renders the '868 patent unenforceable.

SEVENTH DEFENSE

(Limitation on Damages)

40. Merck is barred under 35 U.S.C. § 287 from recovering damages for any alleged act of infringement by Ranbaxy that occurred prior to actual notice of alleged infringement of the '868 patent from Merck.

EIGHTH DEFENSE

(Inequitable Conduct)

41. The '868 patent is unenforceable due to inequitable conduct in its prosecution before the United States Patent and Trademark Office (the "PTO") as more particularly alleged below.

42. The '868 patent issued on September 15, 1992, from U.S. Patent Application Ser. No. 839,725, filed on February 19, 1992 ("'725 application").

43. The '725 application was a continuation of U.S. Patent Application Ser. No. 07/641,317, filed on January 14, 1991, which was a continuation of U.S. Patent

Application Ser. No. 07/244,527, filed on September 9, 1988, which was a continuation of U.S. Patent Application Ser. No. 06/878,391, filed on June 19, 1986, which was a continuation of U.S. Patent Application Ser. No. 06/748,300, filed on June 24, 1985, which was a continuation of U.S. Patent Application Ser. No. 06/465,577, filed on February 10, 1983 (collectively the "'868 patent benefit applications").

44. Continuously during the pendency of each of these applications leading to the '868 patent, from February 10, 1983 until September 15, 1992, Merck, each of the inventors named in the '868 patent, each attorney involved in preparation or prosecution of each application, and every other person who was substantively involved in the preparation or prosecution of the application and who was associated with the inventor, with the assignee or with anyone to whom there was an obligation to assign the application, had a duty to disclose to the PTO all information known to the person to be material to examination of each of the applications.

45. During prosecution of the '868 patent benefit applications, Merck, its prosecuting attorneys, and one or more of the inventors named in the '868 patent violated the duty of disclosure by withholding from the PTO information that was highly material to examination of each of the applications leading to the '868 patent, including copending applications claiming closely-related subject matter and issued patents claiming closely-related subject matter, that a reasonable examiner would have considered highly important in deciding whether to allow any claim of the '868 patent to issue.

46. The highly material information that Merck withheld from the examiners responsible for examining the '725 application and the '868 patent benefit applications included applications and patents claiming combinations of dipeptidase inhibitor compounds as claimed in the '868 patent with thienamycin-type antibiotic compounds. These highly material copending U.S. patent applications and issued U.S. Patents include U.S. Patent No. 4,539,208 (expired) ("'208 patent"), U.S. Patent Application Ser. No. 06/291,711, filed August 10, 1981, U.S. Patent 4,880,793 (expired) ("'793 patent"), U.S.

Patent Application Ser. No. 06/340,152, filed January 18, 1982, U.S. Patent Application Ser. No. 06/394,311, filed July 7, 1982, U.S. Patent Application Ser. No. 06/840,532, filed March 14, 1986, U.S. Patent 5,071,843 ("'843 patent"), U.S. Patent Application Ser. No. 06/605,343, filed April 30, 1984, U.S. Patent Application Ser. No. 06/880,339, filed June 25, 1986, U.S. Patent Application Ser. No. 07/384,845, filed July 24, 1989, U.S. Patent Application Ser. No. 07/741,678, filed January 25, 1990, and U.S. Patent Application Ser. No. 07/671,486 (collectively the "combination applications" and "combination patents").

47. Additional highly material information Merck withheld from the examiners responsible for examining the '725 application and the '868 patent benefit applications included applications and patents claiming methods of using dipeptidase inhibitor compounds as claimed in the '868 patent. These highly material patents and applications included U.S. Patent 4,616,038 ("'038 patent"), U.S. Patent Application Ser. No. 06/340,152, filed January 18, 1982, and U.S. Patent Application Ser. No. 06/747,750, filed January 24, 1985 (collectively the "dipeptidase inhibitor method applications").

48. Claim 1 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 1 of the '208 patent. Specifically, Claim 1 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

49. Claim 7 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 7 of the '208 patent. Specifically, Claim 7 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which

anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

50. Claim 8 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 8 of the '208 patent. Specifically, Claim 8 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

51. Claim 9 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 9 of the '208 patent. Specifically, Claim 9 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

52. Claim 10 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 10 of the '208 patent. Specifically, Claim 10 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

53. Claim 11 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 11 of the '208 patent. Specifically, Claim 11 of the '208 patent recites a

dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

54. Claim 24 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 24 of the '208 patent. Specifically, Claim 24 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

55. Claim 29 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 29 of the '208 patent. Specifically, Claim 29 of the '208 patent claims the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method claimed in Claim 24 of the '868 patent.

56. Claims 30 and 33 of the '208 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claims 30 and 33 of the '208 patent. Specifically, Claims 30 and 33 of the '208 patent claim a method of treatment using a combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method claimed in Claim 24 of the '868 patent.

57. Claim 32 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20,

22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 32 of the '208 patent. Specifically, Claim 32 of the '208 patent claims a method of treatment using the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method claimed in Claim 24 of the '868 patent.

58. Claim 34 of the '208 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 34 of the '208 patent. Specifically, Claim 34 of the '208 patent claims a method of treatment using the combination of a thienamycin-type antibiotic and a dipeptidase inhibitor, which anticipates or makes obvious compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method claimed in Claim 24 of the '868 patent.

59. Claims 1, 7, 8, 9, 10, 11, 24, 29, 30, 32, 33 and 34 of the '208 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 7, 8, 9, 10, 11, 24, 29, 30, 32, 33 and 34 of the '208 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '208 patent and the '868 patent name different inventive entities, and the claims of the '208 patent were material because a reasonable examiner would have considered them important in deciding whether the claims of the '868 patent were barred by 35 U.S.C. §135(b).

60. Claims 1, 7, 8, 9, 10, 11, 24, 29, 30, 32, 33 and 34 of the '208 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 7, 8, 9, 10, 11, 24, 29, 30, 32, 33 and 34 of the '208 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '208 patent and the '868 patent

name different inventive entities, and the claims of the '208 patent were material because a reasonable examiner would have considered them important in deciding whether to require an interference before allowing the claims of the '868 patent to issue.

61. U.S. Patent Application Ser. No. 06/291,711 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/465,577, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 465,577 to issue.

62. U.S. Patent Application Ser. No. 06/291,711 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/748,300, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 465,577 to issue.

63. Claim 1 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 1 of the '038 patent. Specifically, Claim 1 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

64. Claim 2 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 2 of the '038 patent. Specifically, Claim 2 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

65. Claim 3 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 3 of the '038 patent. Specifically, Claim 3 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

66. Claim 4 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 4 of the '038 patent. Specifically, Claim 4 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

67. Claim 5 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 5 of the '038 patent. Specifically, Claim 5 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

68. Claim 6 of the '038 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 5 of the '038 patent. Specifically, Claim 6 of the '038 patent claims a method of using a dipeptidase inhibitor, which anticipates or makes obvious the

compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

69. Claims 1 to 6 of the '038 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1 to 6 of the '038 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '038 patent and the '868 patent name different inventive entities, and the claims of the '038 patent were material because a reasonable examiner would have considered them important in deciding whether the claims of the '868 patent were barred by 35 U.S.C. §135(b).

70. Claims 1 to 6 of the '038 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1 to 6 of the '038 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '038 patent and the '868 patent name different inventive entities, and the claims of the '038 patent were material because a reasonable examiner would have considered them important in deciding whether to require an interference before allowing the claims of the '868 patent to issue.

71. U.S. Patent Application Ser. No. 06/340,152 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/465,577, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/465,577 to issue.

72. U.S. Patent Application Ser. No. 06/747,750 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/748,300, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/748,300 to issue.

73. U.S. Patent Application Ser. No. 06/747,750 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/878,391, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/878,391 to issue.

74. Claims 1 to 6 of the '038 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1 to 6 of the '038 patent define subject matter that is patentably indistinct from Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '038 patent and the '868 patent name different inventive entities, and the claims of the '038 patent were material because a reasonable examiner would have considered them important in deciding whether to allow the claims of the '868 patent to issue.

75. Claim 1 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 1 of the '793 patent. Specifically, Claim 1 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

76. Claim 2 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 2 of the '793 patent. Specifically, Claim 2 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

77. Claim 7 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 7 of the '793 patent. Specifically, Claim 7 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '793 patent, and the method recited in Claim 24 of the '793 patent.

78. Claim 8 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 8 of the '793 patent. Specifically, Claim 8 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '793 patent, and the method recited in Claim 24 of the '868 patent.

79. Claim 9 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 9 of the '793 patent. Specifically, Claim 9 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

80. Claim 10 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 10 of the '793 patent. Specifically, Claim 10 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes

obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

81. Claim 11 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 11 of the '793 patent. Specifically, Claim 11 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

82. Claim 24 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 24 of the '793 patent. Specifically, Claim 24 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

83. Claim 29 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 29 of the '793 patent. Specifically, Claim 29 of the '793 patent claims a composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

84. Claim 31 of the '793 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 31 of the '793 patent. Specifically, Claim 31 of the '793 patent claims a

composition containing a penem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

85. Claims 1, 2, 7, 8, 9, 10, 11, 24, 29, and 31 of the '793 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 7, 8, 9, 10, 11, 24, 29, and 31 of the '793 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '793 patent and the '868 patent name different inventive entities, and the claims of the '793 patent were material because a reasonable examiner would have considered them important in deciding whether the claims of the '868 patent were barred by 35 U.S.C. §135(b).

86. Claims 1, 2, 7, 8, 9, 10, 11, 24, 29, and 31 of the '793 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 Patent, because Claims 1, 2, 7, 8, 9, 10, 11, 24, 29, and 31 of the '793 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '793 patent and the '868 patent name different inventive entities, and the claims of the '793 patent were material because a reasonable examiner would have considered them important in deciding whether to require an interference before allowing the claims of the '868 patent to issue.

87. U.S. Patent Application Ser. No. 06/394,311 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/465,577, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 465,577 to issue.

88. U.S. Patent Application Ser. No. 06/394,311 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/748,300, because a reasonable examiner would have considered patentably indistinct claims of the two

copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/748,300 to issue.

89. U.S. Patent Application Ser. No. 06/840,532 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/878,391, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/878,391 to issue.

90. U.S. Patent Application Ser. No. 06/840,532 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/244,527, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/244,527 to issue.

91. Claim 1 of the '843 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 1 of the '843 patent. Specifically, Claim 1 of the '843 patent claims a composition containing a carbapenem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

92. Claim 2 of the '843 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 2 of the '843 patent. Specifically, Claim 2 of the '843 patent claims a composition containing a carbapenem and a dipeptidase inhibitor and a carrier, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

93. Claim 5 of the '843 patent is information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 Patent, because Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent are invalid for obviousness-type double patenting in view of Claim 5 of the '843 patent. Specifically, Claim 5 of the '843 patent claims a composition containing a carbapenem and a dipeptidase inhibitor, which anticipates or makes obvious the compounds recited in Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, and the method recited in Claim 24 of the '868 patent.

94. Claims 1, 2, and 5 of the '843 patent are information that was material to examination of Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent, because Claims 1, 2 and 5 of the '843 patent define subject matter that is patentably indistinct from and interferes with Claims 1, 2, 9, 19, 20, 22, 23, and 24 of the '868 patent. The '843 patent and the '868 patent name different inventive entities, and the claims of the '843 patent were material because a reasonable examiner would have considered them important in deciding whether to require an interference before allowing the claims of the '868 patent to issue.

95. U.S. Patent Application Ser. No. 06/340,152 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/465,577, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/465,577 to issue.

96. U.S. Patent Application Ser. No. 06/605,343 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/748,300, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/748,300 to issue.

97. U.S. Patent Application Ser. No. 06/880,339 discloses information that was material to examination of U.S. Patent Application Ser. No. 06/878,391, because a

reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 06/878,391 to issue.

98. U.S. Patent Application Ser. No. 06/880,339 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/244,527, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/244,527 to issue.

99. U.S. Patent Application Ser. No. 07/384,845 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/244,527, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/244,527 to issue.

100. U.S. Patent Application Ser. No. 07/471,678 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/244,527, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/244,527 to issue.

101. U.S. Patent Application Ser. No. 07/471,678 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/641,317, because a reasonable examiner would have considered patentably indistinct claims of the two copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/641,317 to issue.

102. U.S. Patent Application Ser. No. 07/681,486 discloses information that was material to examination of U.S. Patent Application Ser. No. 07/839,725, because a reasonable examiner would have considered patentably indistinct claims of the two

copending applications to be important in deciding whether to allow any claim of Application Ser. No. 07/839,725 to issue.

103. On information and belief, Merck, its attorneys, and one or more of the inventors named in the '868 patent intentionally concealed the existence of the '208 patent, the '038 patent, the '793 patent, the '843 patent, the combination applications, and dipeptidase inhibitor method applications identified above from the examiners responsible for examining the '868 patent application and '868 patent benefit applications, with knowledge that these patents and applications were material to examination, and with intent to deceive the examiners responsible for examining the '868 patent application and the '868 patent benefit applications, as more specifically alleged below.

104. Merck attorneys Daniel T. Szura and Robert J. North were each involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/465,577 and U.S. Patent Application Ser. No. 06/291,711. On information and belief, each of these attorneys was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/340,152 to examination of Ser. No. 06/465,577. On information and belief, Daniel T. Szura and Robert J. North concealed the existence of Ser. No. 06/340,152 from the examiner responsible for examination of Ser. No. 06/465,577, with intent to deceive the PTO.

105. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/748,300 and U.S. Patent Application Ser. No. 06/291,711. On information and belief, Robert J. North was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/291,711 to examination of Ser. No. 06/748,300. On information and belief, Robert J. North concealed the existence of Ser. No. 06/291,711 from the examiner responsible for examination of Ser. No. 06/748,300, with intent to deceive the PTO.

106. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/291,711, which issued as the '208 patent. On information and belief, Robert J. North was aware of the '208 patent and was aware of the materiality of the '208 patent to examination of Ser. No. 06/748,300. On information and belief, Robert J. North concealed the allowance and existence of the '208 patent from the examiner responsible for examination of Ser. No. 06/748,300, with intent to deceive the PTO.

107. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/291,711 which issued as the '208 patent. On information and belief, Robert J. North was aware of the '208 patent and was aware of the materiality of the '208 patent to examination of Ser. No. 06/878,391. On information and belief, Robert J. North concealed the allowance and existence of the '208 patent from the examiner responsible for examination of Ser. No. 06/878,391, with intent to deceive the PTO.

108. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/291,711 which issued as the '208 patent. On information and belief, Robert J. North was aware of the '208 patent and was aware of the materiality of the '208 patent to examination of Ser. No. 07/244,527. On information and belief, Robert J. North concealed the allowance and existence of the '208 patent from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

109. Merck attorneys Daniel T. Szura, Raymond M. Speer, and Robert J. North were each involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/465,577 and U.S. Patent Application Ser. No. 06/340,152. On information and belief, each of these attorneys was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/340,152 to examination of Ser. No. 06/465,577. On information and belief, Daniel T. Szura, Raymond M. Speer, and Robert

J. North each concealed the existence of Ser. No. 06/340,152 from the examiner responsible for examination of Ser. No. 06/465,577, with intent to deceive the PTO.

110. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/747,750 and U.S. Patent Application Ser. No. 06/748,300. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/747,750 to examination of Ser. No. 06/748,300. On information and belief, Robert J. North concealed the existence of Ser. No. 06/747,750 from the examiner responsible for examination of Ser. No. 06/748,300, with intent to deceive the PTO.

111. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/747,750 and U.S. Patent Application Ser. No. 06/878,391. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/747,750 to examination of Ser. No. 06/878,391. On information and belief, Robert J. North concealed the existence of Ser. No. 06/747,750 from the examiner responsible for examination of Ser. No. 06/878,391, with intent to deceive the PTO.

112. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/747,750, which issued as the '038 patent. On information and belief, Robert J. North was aware of the '038 patent and was aware of the materiality of the '038 patent to examination of Ser. No. 06/878,391. On information and belief, Robert J. North concealed the allowance and existence of the '038 patent from the examiner responsible for examination of Ser. No. 06/878,391, with intent to deceive the PTO.

113. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/747,750, which issued as the '038 patent. On information and belief, Robert J. North was aware of the '038 patent and was aware of the materiality of the '038 patent to examination of Ser. No. 07/244,527. On information

and belief, Robert J. North concealed the allowance and existence of the '038 patent from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

114. Merck attorneys Daniel T. Szura, Raymond M. Speer, and Robert J. North were each involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/465,577 and U.S. Patent Application Ser. No. 06/394,311. On information and belief, each of these attorneys was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/394,311 to examination of Ser. No. 06/465,577. On information and belief, Daniel T. Szura, Raymond M. Speer, and Robert J. North each concealed the existence of Ser. No. 06/394,311 from the examiner responsible for examination of Ser. No. 06/465,577, with intent to deceive the PTO.

115. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/394,311 and U.S. Patent Application Ser. No. 06/748,300. On information and belief, Robert J. North was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/394,311 to examination of Ser. No. 06/748,300. On information and belief, Robert J. North concealed the existence of Ser. No. 06/394,311 from the examiner responsible for examination of Ser. No. 06/748,300, with intent to deceive the PTO.

116. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/840,532 and U.S. Patent Application Ser. No. 06/878,391. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/840,532 to examination of Ser. No. 06/878,391. On information and belief, Robert J. North concealed the existence of Ser. No. 06/840,532 from the examiner responsible for examination of Ser. No. 06/878,391, with intent to deceive the PTO.

117. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/840,532 and U.S. Patent Application Ser. No.

07/244,527. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/840,532 to examination of Ser. No. 07/244,527. On information and belief, Robert J. North concealed the existence of Ser. No. 06/840,532 from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

118. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/840,532, which issued as the '793 patent, and U.S. Patent Application Ser. No. 07/244,527. On information and belief, Robert J. North was aware of the '793 patent and was aware of the materiality of the '793 patent to examination of Ser. No. 07/244,527. On information and belief, Robert J. North concealed the allowance and existence of the '793 patent from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

119. Merck attorneys Daniel T. Szura, Raymond M. Speer, and Robert J. North were each involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/465,577 and U.S. Patent Application Ser. No. 06/340,152. On information and belief, each of these attorneys was aware of both applications, and was aware of the materiality of information including the claims of Ser. No. 06/340,152 to examination of Ser. No. 06/465,577. On information and belief, Daniel T. Szura, Raymond M. Speer, and Robert J. North each concealed the existence of Ser. No. 06/340,152 from the examiner responsible for examination of Ser. No. 06/465,577, with intent to deceive the PTO.

120. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/605,343 and U.S. Patent Application Ser. No. 06/748,300. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/605,343 to examination of Ser. No. 06/748,300. On information and belief, Robert J. North concealed the existence of Ser. No. 06/605,343 from the examiner responsible for examination of Ser. No. 06/748,300, with intent to deceive the PTO.

121. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/880,339 and U.S. Patent Application Ser. No. 06/878,391. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/880,339 to examination of Ser. No. 06/878,391. On information and belief, Robert J. North concealed the existence of Ser. No. 06/880,339 from the examiner responsible for examination of Ser. No. 06/878,391, with intent to deceive the PTO.

122. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 06/880,339 and U.S. Patent Application Ser. No. 07/244,527. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 06/880,339 to examination of Ser. No. 07/244,527. On information and belief, Robert J. North concealed the existence of Ser. No. 06/880,339 from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

123. Merck attorney Robert J. North was involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/384,845 and U.S. Patent Application Ser. No. 07/244,527. On information and belief, Robert J. North was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 07/384,845 to examination of Ser. No. 07/244,527. On information and belief, Robert J. North concealed the existence of Ser. No. 07/384,845 from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

124. Merck attorneys Robert J. North and Frank P. Grassler were involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/471,678 and U.S. Patent Application Ser. No. 07/244,527. On information and belief, Robert J. North and Frank P. Grassler were aware of both applications and were aware of the materiality of information including the claims of Ser. No. 07/471,678 to examination of Ser. No. 07/244,527. On information and belief, Robert J. North and Frank P. Grassler concealed

the existence of Ser. No. 07/471,678 from the examiner responsible for examination of Ser. No. 07/244,527, with intent to deceive the PTO.

125. Merck attorney Frank P. Grassler was involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/471,678 and U.S. Patent Application Ser. No. 07/641,317. On information and belief, Frank P. Grassler was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 07/471,678 to examination of Ser. No. 07/641,317. On information and belief, Frank P. Grassler concealed the existence of Ser. No. 07/471,678 from the examiner responsible for examination of Ser. No. 07/641,317, with intent to deceive the PTO.

126. Merck attorney Frank P. Grassler was involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/681,486 and U.S. Patent Application Ser. No. 07/839,725. On information and belief, Frank P. Grassler was aware of both applications and was aware of the materiality of information including the claims of Ser. No. 07/681,486 to examination of Ser. No. 07/839,725. On information and belief, Frank P. Grassler concealed the existence of Ser. No. 07/681,486 from the examiner responsible for examination of Ser. No. 07/839,725, with intent to deceive the PTO.

127. Merck attorney Frank P. Grassler was involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/681,486, which issued as the '843 patent, and U.S. Patent Application Ser. No. 07/641,317. On information and belief, Frank P. Grassler was aware of the '843 patent and was aware of the materiality of the '843 patent to examination of Ser. No. 07/641,317. On information and belief, Frank P. Grassler concealed the allowance and existence of the '843 patent from the examiner responsible for examination of Ser. No. 07/641,317, with intent to deceive the PTO.

128. Merck attorney Frank P. Grassler was involved in preparation or prosecution of U.S. Patent Application Ser. No. 07/681,486, which issued as the '843 patent, and U.S. Patent Application Ser. No. 07/839,725. On information and belief, Frank P. Grassler was aware of the '843 patent and was aware of the materiality of the

'843 patent to examination of Ser. No. 07/839,725. On information and belief, Frank P. Grassler concealed the allowance and existence of the '843 patent from the examiner responsible for examination of Ser. No. 07/839,725, with intent to deceive the PTO.

129. The '868 patent is unenforceable because Merck and its attorneys including at least Daniel T. Szura, Raymond M. Speer, Robert J. North, and Frank P. Grassler violated their duty of good faith in dealing with the PTO under 37 C.F.R. §1.56, by failing to disclose the '208 patent, the '038 patent, the '793 patent and the '843 patent and the applications leading to issuance of these patents to the examiners responsible for examining the '868 patent application and the '868 benefit applications, as alleged more fully above. On information and belief, Merck and its attorneys intentionally concealed the existence of the '208 patent, the '038 patent, the '793 patent and the '843 patent and the applications leading to issuance of these patents, from the examiners responsible for examining the '868 patent application and the '868 benefit applications, with intent to deceive the PTO.

RANBAXY'S COUNTERCLAIMS

Defendants/Counterclaimants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy") hereby allege the following counterclaims against Plaintiff/Counterdefendant Merck & Co., Inc. ("Merck"), for declaratory judgment that U.S. Patent No. 5,147,868 ("'868 patent") is invalid, unenforceable, and/or not infringed by the proposed injectable products comprising imipenem and cilastatin sodium ("proposed injectable product") in Ranbaxy's Abbreviated New Drug Application ("ANDA") and associated drug master file(s).

PARTIES, JURISDICTION AND VENUE

130. ~~41.~~ Ranbaxy Inc. is a corporation organized and existing under the laws of the state of Delaware, and has a principal place of business at 600 College Road East, Princeton, New Jersey, 08540. Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, having a principal place of business in Gurgaon (Haryana) India.

131. ~~42.~~ On information and belief, Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey.

132. ~~43.~~ This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367(a), 2201 and 2202, and 35 U.S.C. § 1, *et seq.*

133. ~~44. Merck has submitted to the personal jurisdiction of this Court.~~

134. ~~45. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400~~ and because this suit was filed in this district by Merck.

THE CONTROVERSY

135. ~~46.~~ This is an action based on an actual controversy between Ranbaxy and Merck concerning the invalidity and/or noninfringement of the '868 patent-in-suit, and Ranbaxy's right to continue to seek approval of its ANDA for its proposed injectable products, and upon approval by the FDA, to manufacture use, sell and offer to sell and import into the United States its proposed injectable products.

136. ~~47. United States Patent No. 5,147,868~~The '868 patent is entitled "Thienamycin Renal Peptidase Inhibitors," bears an issue date from the United States Patent and Trademark Office of September 15, 1992, lists Merck & Co., Inc. as the assignee, and lists as inventors Donald W. Graham, Edward F. Rogers and Frederick M. Kahan.

137. ~~48.~~ Merck has represented that one or more claims of the '868 patent appear to cover the compounds cilastatin and cilastatin sodium. Merck has represented that it currently sells PRIMAXIN® I.M., which is an injectable suspension containing imipenem and cilastatin sodium, and PRIMAXIN® I.V., which is an injection containing imipenem and cilastatin sodium.

138. ~~49.~~ Ranbaxy has submitted, and is continuing to seek FDA approval of, ~~an ANDA~~anANDA directed to products containing imipenem/cilastatin sodium, and approval to engage in the commercial manufacture, use, offer for sale, sale, and importation into the United States, its proposed injectable products under that ANDA, which Merck alleges infringes the '868 patent-in-suit.

139. ~~50.~~ By letter of January 22, 2007, Ranbaxy informed Merck that it had submitted to FDA its ANDA directed to its proposed injectable product, and stated that ~~the manufacture, use, offer for sale or sale of its proposed injectable products would not infringe any valid claim of Merck's '868 patent.~~

140. ~~51.~~ Ranbaxy also informed Merck that it planned to begin marketing of its proposed injectable products immediately upon FDA approval of its ANDA. Ranbaxy sought from Merck a covenant not to sue on the '868 patent, and provided to Merck an offer of confidential access to its ANDA and its DMF(s) for the purpose of determining whether to grant Ranbaxy a covenant not to sue. Merck did not covenant not to sue Ranbaxy, and filed this suit April 30, 2007.

141. ~~52.~~ Ranbaxy has undertaken substantial efforts in developing and seeking approval for its imipenem/cilastatin proposed injectable products set forth in its ANDA.

142. ~~53.~~ In view of the foregoing, an actual justiciable controversy exists by virtue of Ranbaxy's notification to Merck of its ANDA filing, Ranbaxy's request for a covenant not to be sued on the '868 patent, and Merck's subsequent filing of the present suit as to Ranbaxy's right to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, sale, and importation into the United States, its proposed injectable products described in its ANDA.

COUNTERCLAIM I

(Noninfringement of '868 Patent)

143. ~~54.~~ Ranbaxy repeats and realleges paragraphs ~~41–53~~130-142 above as if fully set forth herein.

144. ~~55.~~ Ranbaxy has not manufactured, used, sold, or offered for sale in the United States, or imported into the United States, any products that infringe any valid claim of the '868 patent, either literally or under the doctrine of equivalents.

145. ~~56.~~ Ranbaxy's proposed injectable products do not infringe ~~any valid claim of the '868 patent, either literally or under the doctrine of equivalents and Ranbaxy~~and ~~does not and has not induced infringement or contributed to infringement of any valid claim of the '868 patent, either literally or under the doctrine of equivalents.~~

146. ~~57.~~ Merck is estopped from asserting any scope for one or more of the claims of the '868 patent which would cover Ranbaxy's proposed injectable products because of amendments, representations, assertions, disclaimers and/or admissions made during the course of proceedings in the United States Patent and Trademark Office ("PTO") during prosecution of the applications leading to the issuance of the '868 patent applications and during the prosecution of all applications in the family beginning with the filing of Application Serial No. 05/927,213 and other Merck patents/applications and foreign counterparts of any such applications or patents, including but not limited to, prosecution disclaimer.

COUNTERCLAIM II

(Invalidity of '868 Patent)

147. ~~58.~~ Ranbaxy repeats and realleges paragraphs ~~41–57~~130-146 above as if fully set forth herein.

148. ~~59.~~ Each and every claim of the '868 patent is invalid for failure to meet the statutory requirements of Title 35 of the United States Code, including, but not limited to, the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

149. ~~60.~~ Each and every claim of the '868 patent is invalid for failing to meet judicially-created requirements for patentability and enforceability of patents, including but not limited to, obviousness-type double patenting based on U.S. Patent No. 4,539,208.

COUNTERCLAIM III

(Unenforceability)

150. ~~61.~~ Ranbaxy repeats and realleges paragraphs ~~41-60~~130-149 above as if fully set forth herein.

151. ~~62. Merck unfairly and inequitably filed multiple continuation applications over a long period of time. Because Merck failed to timely prosecute the '868 patent, the~~ '868 patent is unenforceable due to prosecution laches.

COUNTERCLAIM IV

(Unenforceability)

152. Ranbaxy repeats and realleges paragraphs 130-151 above as if fully set forth.

153. The '868 patent is unenforceable due to inequitable conduct by Merck and its attorneys in prosecuting the '868 patent before the United States Patent and Trademark Office as alleged in Ranbaxy's Eighth Defense above (paragraphs 41-129).

154. Ranbaxy therefore seeks and is entitled to a judicial determination that the '868 patent is unenforceable for inequitable conduct before the PTO.

DEMAND FOR JUDGMENT

WHEREFORE, Ranbaxy prays for the following relief:

(1) That any and all relief requested by Merck, as set forth in the Prayer of Relief of the Complaint, be denied and that the Complaint be dismissed with prejudice;

(2) That a judgment be entered declaring that Ranbaxy has not and does not infringe any claim of U.S. Patent No. 5,147,868;

(3) That a judgment be entered declaring all claims of U.S. Patent No. 5,147,868 invalid and/or unenforceable;

(4) That Ranbaxy has a lawful right to seek and obtain FDA approval of its ~~ANDA~~ANDAs for its imipenem/cilastatin sodium injectable products, and that based on the noninfringement, invalidity and/or unenforceability of U.S. Patent No. 5,147,868, Ranbaxy has a right to import, manufacture, use, offer for sale and sell its proposed imipenem/cilastatin sodium injectable products once approved by FDA;

(5) That Merck, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them, be preliminarily and permanently enjoined from threatening or initiating further infringement litigation against Ranbaxy or any of its customers, dealers or suppliers, or any prospective sellers, dealers, distributors or customers of Ranbaxy, or charging any of them either orally or in writing with infringement of U.S. Patent No. 5,147,868;

(6) That a judgment be entered declaring this case to be exceptional within the meaning of 35 U.S.C. §285 and that Ranbaxy is entitled to recover its reasonable attorneys' fees upon prevailing in this action;

(7) That Ranbaxy be awarded costs, attorneys' fees and other relief, both legal and equitable, to which they may be justly entitled; and

(8) That Ranbaxy be awarded such other relief as this Court deems just and proper.

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Dated: ~~June 21, 2007~~January 11, 2008

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., Inc. Plaintiff, v. RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Defendants.	C.A. No. 07-229 (GMS)
RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Counterclaim Plaintiffs, v. MERCK & CO., Inc. Counterclaim Defendant.	

ORDER

WHEREAS, Defendants Ranbaxy, Inc. and Ranbaxy Laboratories Limited (collectively, "Ranbaxy") having filed a Motion for Leave to Amend and Supplement its Answer and Counterclaims (the "Motion") and the Court having considered the briefing submitted in conjunction with the Motion;

IT IS HEREBY ORDERED this ___ day of _____, 2008 that Ranbaxy's Motion for Leave to Amend and Supplement its Answer and Counterclaims is GRANTED. The Amended and Supplemental Answer and Counterclaims is deemed served and filed as of the date of this Order.

_____
Chief Judge, United States District Court